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EXAMINER	
COBANOGLU, DILEK B	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/772,394	STANGEL, PETER	
	Examiner	Art Unit	
	Dilek B. Cobanoglu	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/14/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This is a communication to the Request for Continued Examination (RCE) mailed on 07/17/2006. Claim 16 has been canceled. Claims 1-4, 7-10, 12-15, 17-20, 22-23, 25-26 and 29 have been amended.

Claim Rejections - 35 USC § 112

2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. As per claim 1, it is unclear what are the structures of the system, the system consists of user interface, navigation and verification modules, which are not real apparatuses. Also, there is no interconnection between the modules.

B. As per claim 12, it is not clear what is/are the structure(s) of the claim. There is no structural limitation and practical application resulted by "the set of lists" recited in the body of the claim.

C. As per claims 13, 14, 23-28 it is unclear what are the structures of claims. In addition, it is unclear how these claims further limit the independent claim 12.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-7 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

A. As per apparatus claims 1-7, 12-14 and 23-28, the claims recite a collection of software modules and an interactive set of lists, which appears to be a collection of non-functional descriptive material. The claims are therefore considered non-statutory because they are not capable of causing a functional change in a computer. As drafted, the claim fails to define any structural and functional interrelationships between the software modules and other elements of a computer that permit the computer program's function to be realized. (See MPEP section 2106)

B. Method claim 18 recites the steps for providing a selection interface and allowing the user to select a parameter, which do not produce a processing result. For claimed invention to be statutory, the claimed invention must produce a useful, concrete and tangible result. Under this analysis, the present language of claim 18 fails to recite a useful result, and therefore, considered non-statutory. (See MPEP section 2106)

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being unpatentable by Jacobs et al. (hereinafter Jacobs) (U.S. Patent No. 6,049,794).

A. As per claim 1, Jacobs discloses a computer implemented system, comprising:

i. At least one user interface module, wherein the at least one interface module facilitates generation of an electronic record of a patient clinical encounter by presenting a user interface comprising a plurality of fields to a user and receiving data from the user via at least a first subset of the plurality of fields, wherein the plurality of fields are arranged as on a clinical chart, wherein at least a second subset of the plurality of fields comprises a list of values, wherein the electronic record is to be reviewed by a healthcare reviewing organization, and wherein the user interface module facilitates selection of at least a diagnosis (Jacobs; col. 2, line 65 to col. 3, line 12, col. 5, lines 32-38);

ii. at least one navigation module, wherein the at least one navigation module modifies the fields presented by the at least one user interface module in response to data entered into the user interface module (Jacobs; col. 6, lines 1-6 and lines 14-18); and

iii. a verification module for determining an authorization level for the diagnosis by referring to at least data in identified fields, the verification module determining said authorization level prior to submission of the

clinical record to a server computer (Jacobs; col. 6, lines 19-24 and col. 8, lines 2-8).

B. As per claim 2, Jacobs discloses the system of claim 1, wherein said user interface module further facilitates selection of one or more criteria corresponding to the a-selected diagnosis and wherein the one or more criteria are selected by the navigation module from a set of criteria stored in a criteria database (Jacobs; col. 5, lines 7-12 and Fig. 2, 4).

C. As per claim 3, Jacobs discloses the system of claim 2, wherein said authorization level is determined at least in part by the selected criteria (Jacobs; col. 8, lines 2-8).

D. As per claim 4, Jacobs discloses the system of claim 1, wherein the user interface module presents the plurality of fields in is a single screen, and whereby the user need not scroll the screen when entering data in the plurality of fields (Jacobs; col. 6, lines 45-60).

E. As per claim 5, Jacobs discloses the system of claim 1, wherein said verification module is coupled to a rule database which stores rules on the server computer and is employed by the verification module in determining said authorization level (Jacobs; abstract, col. 2, line 65 to col. 3, line 12).

F. As per claim 6, Jacobs discloses the system of claim 5, wherein the rule database stores at least two levels of rules, said levels comprising:

i. a criteria level, the criteria level rules determining a criteria status by referring to data from the identified fields of said clinical record (Jacobs; col. 5, lines 7-12, col. 8, lines 2-8); and

ii. a diagnosis level, the diagnosis level rules determining a diagnosis authorization level by referring to the criteria status of associated criteria (Jacobs; abstract, col. 5, lines 7-12).

G. As per claim 7, Jacobs discloses the system of claim 1, wherein the user interface module is implemented on a client computer, further comprising:

i. a first computer database, housed on the server computer, wherein the first computer database is associated with a user interface module, wherein the first computer database stores forms and controls employed in the generation of the user interface, and wherein the user interface module causes the forms and controls to be presented in a format similar to a clinical chart (Jacobs; abstract, col. 5, lines 7-12, Fig. 5);

ii. a second computer database, housed on the server computer, wherein the second computer database is associated with the navigation module, and wherein the second computer database stores hierarchical information representing data selections available to a user (Jacobs; abstract, col. 2, line 65 to col. 3, line 12); and,

iii. a third computer database, housed on the server computer, wherein the third computer database is associated with the verification module, wherein the third computer database stores criteria rules, and

wherein the criteria rules are evaluated on the client computer to determine in real-time whether each data entry meets one or more criteria for determining an authorization level (Jacobs; abstract, col. 2, line 65 to col. 3, line 12).

H. As per claim 8, Jacobs discloses a method for facilitating the submission of a clinical record for automated processing, comprising:

i. providing at least one selection interface, wherein the selection interface facilitates selection by a user of one of a plurality of predetermined clinical data values, the predetermined clinical values comprising at least a record of the symptoms associated with a patient and a diagnosis (Jacobs; abstract, col. 6, lines 1-4);

ii. receiving a selection from said selection interface (Jacobs; col. 6, lines 5-9); and

iii. providing at least one data field in response to said selection, wherein the data field is a quantified data field associated with an objective criteria, and whereby said quantified data field facilitates automated processing of said clinical record (Jacobs; col. 6, lines 14-24).

7. Claims 9-11, 18-22, 29 are rejected under 35 U.S.C. 102(e) as being unpatentable by Bond et al. (hereinafter Bond) (U.S. Patent No. 6,177,940 B1).

A. As per claim 9, Bond discloses a method for entering medical diagnosis-based data, comprising:

i. entering a diagnosis into a database residing on a server computer (Bond; col. 3, lines 40-48, col. 5, line 66 to col. 6, line 9);

ii. entering a criteria into the database residing on the server computer, the criteria associated with a rule required for confirming the entered diagnosis, the criteria associated with at least one finding (Bond; col. 6, lines 10-24);

iii. entering into the database residing on the server computer data corresponding to at least a subset of the at least one finding associated with the entered criteria (Bond; col. 6, lines 10-24); and

iv. generating an electronic clinical record based on the entered data (Bond; col. 12, lines 9-17).

B. As per claim 10, Bond discloses the method of claim 9, further comprising a step of entering additional data corresponding to the at least one finding (Bond; col. 7, lines 20-29, col. 17, lines 26-31).

C. As per claim 11, Bond discloses the method of claim 9, further comprising a step of entering a request for additional information by employing an additional request selection interface (Bond; col. 7, lines 20-29).

D. As per claim 18, Bond discloses a method for facilitating the single screen submission of patient clinical data in a computer implemented patient care review system, comprising:

i. providing a clinical element selection interface, the clinical element selection interface facilitating the selection of a clinical element, wherein

the selectable clinical elements comprise at least one of history and exam (Bond; col. 6, lines 1-4, Fig. 4);

ii. providing a system/group selection interface, the system/group selection interface facilitating the selection of a system/group associated with the selected clinical element (Bond; col. 6, lines 1-4, Fig. 4); and

iii. providing a parameter selection interface, the parameter selection interface facilitating the selection of a parameter associated with the selected system/group (Bond; col. 6, lines 14-24);

iv. wherein the element selection interface, the system/group selection interface, and the parameter selection interface are displayed within a single screen (Bond; col. 7, lines 21-26, Fig. 7, 9).

H. As per claim 19, Bond discloses a method for providing an indication of appropriateness of a patient clinical encounter to a user of an electronic clinical charting system that facilitates the submission of diagnosis-relevant clinical data associated with the patient clinical encounter, comprising:

i. providing a criteria selection interface, wherein the criteria selection interface allows the user to select a diagnosis-based criteria (Bond; col. 6, lines 14-24);

ii. receiving diagnosis related data from the user (Bond; col. 6, lines 1-9);

iii. applying a verification rule to the received data (Bond; col. 8, lines 43-47); and

iv. providing a verification result indication, the indication provided within each selected criterion in the criteria selection interface, and wherein the indication conveys each criterion authorization level (Bond; col. 8, lines 23-56).

I. As per claim 20, Bond discloses the method of claim 19, wherein patient clinical encounter information is presented on a user computer with relevant clinical data in clinical format that is familiar to clinicians and healthcare reviewers (Bond; abstract, col. 2, line 65 to col. 3, line 12).

J. As per claim 21, Bond discloses the method of claim 20, wherein criteria guided two-step clinical entry is done by users who are at least one of clinicians or clinician aids at the site of the patient encounter (Bond; col. 2, line 65 to col. 3, line 12, col. 5, lines 32-35).

K. As per claim 22, Bond discloses the method of claim 21 wherein two-step clinical entry of relevant clinical data is made in a screen display requiring no scrolling and wherein the screen display expedites transformation of physical patient charts into electronic format for review by health care review organizations (Bond; col. 5, lines 52-54, Fig. 5-10).

L. As per claim 29, Bond discloses an electronic clinical record review system comprising:

i. a user interface, wherein the user interface prompts for clinically relevant inputs which are used to generate an electronic record of a patient clinical encounter (Bond; abstract, col. 3, lines 11-16, lines 40-47);

ii. a communications interface, whereby the electronic clinical record is transmitted to a health care reviewing organization review (Bond; col. 2, lines 52-65, col. 6, lines 35-48); and

iii. a clinical data evaluation module, wherein the clinical data evaluation module automatically evaluates clinical data stored in the electronic clinical record for individual criteria and for the patient clinical encounter, the clinical data comprising patient symptoms (Bond; col. 19, lines 21-34).

8. Claims 12-14, 23-28 are rejected under 35 U.S.C. 102(e) as being unpatentable by Roberge et al. (hereinafter Roberge) (U.S. Patent No. 6,381,611 B1).

A. As per claim 12, Roberge discloses an interface for entering data for evaluation of a clinical encounter, comprising: an interactive set of lists, wherein each of the lists in the interactive set of lists has its own domains, wherein each of the lists in the interactive set of lists is displayed as a separate pop-up button list, and wherein the interactive set of lists is formatted to be similar to a clinical chart (Roberge; abstract, col. 6, lines 10-30, Fig. 1, 7, 8).

B. As per claim 13, Roberge discloses the interface of claim 12 further comprising a display area, wherein the display area displays a parameter and at least one corresponding finding, by displaying each parameter proximate to the associated at least one finding (Roberge; col. 8, lines 43-45, Fig. 15).

C. As per claim 14, Roberge discloses the interface of claim 12 further comprising a data entry area, wherein the data entry area is adapted to facilitate

entry of more than one finding for a parameter (Roberge; col. 5, lines 63-66, Fig. 6b).

D. As per claim 23, Roberge discloses the interface of claim 12, wherein at least four pop-up button lists are displayed and include at least one of an Element pop-up button list, a System/Group button list, a Parameter pop-up button list and a Finding pop-up button list (Roberge; col. 6, lines 10-17, Fig. 1).

E. As per claim 24, Roberge discloses the interface of claim 23, wherein a selection in one pop-up list populates the next pop-up button list (Roberge; abstract, col. 7, lines 59-65, Fig. 1, 13).

F. As per claim 25, Roberge discloses the interface of claim 23, wherein

a selection in an Element pop-up button list populates a System/Group pop-up, button list, a selection in the System/Group pop-up button list populates a Parameter pop-up button list, and a selection in a Finding pop-up button list either a) enters the selected Finding with the selected Parameter into a chart note data field in the clinically formatted on-screen display; or b) prompts a user to enter a numeric value, selected to be associated with the Finding, and wherein the Finding and its associated value, along with the selected Parameter, are entered into a chart note data field in the clinically formatted on screen display (Roberge; abstract, col. 6, lines 18-42, col. 7, lines 50-57, col. 8, lines 39-45 and Fig. 1, 15).

G. As per claim 26, Roberge discloses the interface of claim 25, wherein a selection in a criteria pop-up button list populates the Element pop-up button list,

System/Group pop-up button list, Parameter pop-up button list and Finding pop-up button list to enable the user to select the Finding (Roberge; col. 3, line 64 to col. 4, line 15, Fig. 1, 9).

H. As per claim 27, Roberge discloses the interface of claim 26, wherein only two steps are necessary to enter diagnosis-relevant clinical date: a) a selection in the criteria pop-up list which either prompts selection of a finding from the Finding List, or b) for a numerical finding, selects the finding and prompts for the numerical value (Roberge; abstract, col. 6, lines 18-42, col. 7, lines 50-57, col. 8, lines 39-45 and Fig. 1, 15).

I. As per claim 28, Roberge discloses the interface of claim 27, where similarly a selection in the additional info pop up list sets the Element list, System/Group list, Parameter list and Finding list to enable the user to select the Finding (Roberge; col. 9, line 25 to col. 10, line 11).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 15 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (hereinafter Jacobs) (U.S. Patent No. 6,049,794) in view of Johnson et al. (hereinafter Johnson) (U.S. Patent No. 5,664,109).

A. As per claim 15, Jacobs discloses a method for processing patient clinical data by a health care organization, comprising:

i. establishing a server computer, wherein a plurality of forms facilitating the entry of patient clinical data in clinical chart form are stored on the server computer;

ii. establishing a user site (Jacobs; col. 2, line 65 to col. 3, line 12);

iii. interconnecting the server computer and the user site;

iv. retrieving from the server computer at least one of the plurality of forms for display and editing at the user site (Jacobs; col. 5, lines 19-31);

v. configuring at least a first subset of the forms to apply a first set of rules to at least a first subset of inputs entered into the first subset of forms, wherein the first set of rules authorizes at least one diagnosis based on associated clinical patient encounter criteria (Jacobs; col. 6, lines 45-60);

vi. configuring at least a second subset of the forms to apply a second of set of rules to at least a second subset of inputs entered into the second subset of forms, wherein the second set of rules evaluates clinical patient encounter data (Jacobs; col. 6, lines 45-60);

vii. receiving patient clinical encounter data from at least one user interacting with the user site (Jacobs; col. 6, lines 45-60); and

viii. processing the received patient clinical encounter data automatically in accordance with the first and second set of rules (Jacobs; col. 8, lines 23-56).

Jacobs fails to expressly teach the server computer, per se, since it appears that Jacobs is more directed to a personal computer where the system is run. (Jacobs; abstract). However, this feature is well known in the art, as evidenced by Johnson.

In particular, Johnson discloses a server computer, which interconnects with a user interface (Johnson; abstract, col. 2, lines 38-41, Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Jacobs with the motivation of serving plurality of subscribers (Johnson; col. 4, lines 41-51)

B. As per claim 17, Jacobs discloses the method of claim 15, further comprising providing an indication to a user of the user site regarding an authorization level for the entered data, wherein the indication is provided before the user submits the form (Jacobs; col. 6, lines 1-24).

Response to Arguments

11. Applicant's arguments with respect to claims 1-15, 17-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but nor used prior art teach Medical network management system and process 5471382 A, Medical network management system and process 5764923 A, Human factored interface incorporating adaptive pattern recognition based controller apparatus 5774357 A, System and method for managing patient medical records 5772585 A, Network media access control system for encouraging patient compliance with a treatment plan 5933136 A, Medical network management article of manufacture 5964700 A, Integrated system and method for ordering and cumulative results reporting of medical tests 6018713 A, Integrated emergency medical transportation database system 6117073 A, Health care data manipulation and analysis system 6230142 B1, Disease management system and method including correlation assessment 20010012913, Method and system for automated data storage and retrieval 6308171 B1, System and method for providing prescription assistance for indigent patients using programs provided by pharmaceutical manufacturers 20010037218, Augmentation system for documentation 20010042080, System, method and article of manufacture for managing a medical services network 20010051881, Provider claim editing and settlement system 6341265 B1, Media

recording device with packet data interface 20020151992, Apparatus and method for computerized multi-media data organization and transmission 6597392 B1, Health monitoring and diagnostic device and network-based health assessment and medical records maintenance system 6602469 B1.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBC
Art Unit 3626
10/04/2006

C. LUKE GILLIGAN
PATENT EXAMINER